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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,295	02/24/2004	Yoseph Shaaltiel	27557	2272

7590
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01/08/2008

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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01/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,295

Applicant(s)

SHAALTIEL, YOSEPH

Examiner

William H. Beisner

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 99-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 99-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/19/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in the reply filed on 10/15/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The information disclosure statement filed 10/19/2005 has been considered and made of record.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 99-102, 104, 108-114, and 116-121 are rejected under 35 U.S.C. 102(b) as being anticipated by Arad et al.(US 5,534,417).

With respect to claim 99, the reference of Arad et al. discloses a system (See Figures 1 and 2a) for culturing cells which includes a container (5,6) which comprises a harvester (10). Note the container (5,6) is considered sterilizable and disposable. With respect to the recited "a

flow controller", the harvester (10) is positioned above the bottom of the container such that a portion of the culture medium would remain in the container when medium is removed using harvester (10).

With respect to claims 100 and 101, the device is capable of culturing the cells recited in these claims.

With respect to claim 102, the reference of Arad et al. disclose PVC as a possible material of construction (See column 3, lines 44-53).

With respect to claim 104, the reference of Arad et al. discloses the use of bubbling device (7).

With respect to claim 108, the container has a cylindrical geometrical configuration.

With respect to claims 109 and 110, in the absence of further positively recited structure, the bubbler of the reference of Arad et al. is considered to be capable of providing bubbles of the claimed size since the size of the bubbles depends on factors such as the operation pressures and the properties of the culture medium.

With respect to claim 111, the harvester (10) is positioned above the bottom of the container such that a portion of the culture medium would remain in the container when medium is removed using harvester (10).

With respect to claim 112, the bottom of the container includes upwardly sloping walls (See Figures 1 and 2a).

With respect to claim 113, the reference discloses that the container can have a perimeter between 5 and 100 cm and a height between 100 and 250 cm (See column 3, line 65, to column 4, line 5).

With respect to claim 114, the device includes a support structure (4).

With respect to claim 116, the device includes a battery of containers (5,6)(See Figures 1 and 2a).

With respect to claim 117, the device includes a support structure (4).

With respect to claim 118, the device includes an additive inlet (10) connected to common inlet (9).

With respect to claim 119, the device includes a common harvesting piping (9).

With respect to claims 120 and 121, the device includes a common air inlet piping disposed within element (4) (See column 4, lines 51-55).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Kalfon (EP 343 885).

The reference of Arad et al. has been discussed above.

Claim 103 differs by reciting that the sidewalls of the container are made of a laminate of layers.

The reference of Kalfon discloses that it is conventional in the art of flexible bioreactors to manufacture the sidewalls of the container using a laminated material (See column 2, lines 32-46).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to manufacture the containers of the primary reference using laminated sheet material for the known and predicable result of using an alternative means of manufacture recognized in the art while providing a container of the required size and strength.

8. Claims 105 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Hitzman (US 4,519,984).

The reference of Arad et al. has been discussed above.

While the reference of Arad et al. discloses the use of a bubbling device, claims 105 and 106 differ by reciting that each container includes a plurality of bubbling device.

The reference of Hitzman discloses that it is conventional in the art of bioreactors to provide a plurality of bubbling devices (18) in each bioreactor vessel.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the bioreactor containers of the primary reference

with a plurality of gas bubblers or spargers for the known and predictable result of bubbling the reactor vessel using an alternative means recognized in the art to achieve the same result, bubbling the culture medium with air and/or oxygen.

9. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Kobayashi (US 5,565,015).

The reference of Arad et al. has been discussed above.

Claim 107 differs by reciting that the container has a box-like geometrical configuration.

The reference of Kobayashi discloses that it is conventional in the art to construct a bioreactor vessel using a box-like geometrical configuration (See Figure 3). The reference discloses that the container can be made of various shapes including tubular and a gusset type bag (See column 1, lines 53-61).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture the container from any of the vessel shapes that are conventional in the art for the known and predictable result of providing a bioreactor vessel that can support the weight of its contents during use and can withstand sterilization conditions. The exact dimensions of the container would have been well within the purview of one having ordinary skill in the art while maintaining the required reaction conditions.

10. Claim 115 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arad et al.(US 5,534,417) in view of Whitney (GB 2 202 549).

The reference of Arad et al. has been discussed above.

Claim 115 differs by reciting that the device includes a rigid cylindrical frame including a conical bottom.

The reference of Whitney discloses that it is conventional in the art to support a flexible bioreactor vessel using either a frame similar to the primary reference (See Figure 1) or using a cylindrical frame with a conical bottom (See Figure 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a cylindrical frame as disclosed by the reference of Whitney to support a reactor vessel for the known and predictable result of providing an alternative means recognized in the art to achieve the same result, support a flexible reactor vessel.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 99-121 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,391,638. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 99-121 are generic to all that is recited in claims 1-45 of U.S. Patent No. 6,391,638. That is, claims 1-45 of U.S. Patent No. 6,391,638 fall entirely within the scope of claims 99-121 or, in other words, claims 99-121 are anticipated by claims 1-45 of U.S. Patent No. 6,391,638.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner
Art Unit 1797

WHB